

ASSESS BIO-RISK. STRENGTHEN BIOLOGICAL SAFETY.

End-to-end biocompatibility evaluation, biological safety strategy & alignment with ISO 10993-1:2025.

Build a coherent biological safety case connecting device characteristics, existing evidence, testing strategy and regulatory documentation.

YOUR CHALLENGES



BIOLOGICAL EVALUATION STRATEGY How to define the biological evidence required based on device materials, nature and duration of contact, and available data?



EVIDENCE & TESTING JUSTIFICATION How to determine which existing evidence is sufficient and where additional biological testing is scientifically justified?



BEP / BER CONSISTENCY How to ensure the Biological Evaluation Plan and Report form a coherent, traceable safety case aligned with ISO 10993-1:2025 and regulatory expectations?

OUR APPROACH

01 ASSESS

- Critical review of existing biocompatibility data and normative impact analysis
- Definition of customized biological evaluation strategies and worst-case rationale
- Drafting of Biological Evaluation Plans (BEP) compliant with ISO 10993-1:2025



02 IMPLEMENT

- Testing laboratory selection, protocol optimization, and external study management
- Coordinating and interpreting applicable biocompatibility testing
- Integrate available evidence and test results into the Biological Evaluation Report (BER) and biological risk files



03 ASSURE

- Specialized training courses covering ISO 10993-1:2025 and ISO 10993-17:2023
- Maintain alignment with ISO 10993-1:2025 and other applicable parts of the ISO 10993 series
- Support biological safety questions during Notified Body or regulatory review

YOUR BENEFITS



CLEAR BIOLOGICAL EVALUATION STRATEGY

Biological evidence requirements defined according to device characteristics, available data and applicable standards.



SCIENTIFICALLY JUSTIFIED TESTING

Existing evidence and biological testing integrated through a documented scientific rationale, avoiding testing that is not justified by the biological evaluation.



COHERENT BIOLOGICAL SAFETY EVIDENCE

EBEP, test evidence and BER connected through a clear, traceable rationale supporting regulatory review.

READY TO STRENGTHEN YOUR BIOLOGICAL SAFETY EVIDENCE?

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